"RESPONSE UNDER 37 CFR 1.116-
EXPEDITED PROCEDURE EXAMINING
GROUP ____"

0327-0759-0

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:	: EXAMINER: WEBER
NAOKO TSUJI ET AL.	: GROUP ART UNIT: 1651
SERIAL NO: 09/220,691	: CPA FILED: November 11, 2001
FILED: DECEMBER 28, 1998	: RCE FILED: February 1, 2002

FOR: METHOD OF INHIBITING HAIR GROWTH

REQUEST FOR RECONSIDERATION

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Responsive to the Official Action dated February 27, 2003, and accompanied by a petition for a one-month extension of time and the appropriate fees, Applicants respectfully request reconsideration of the above identified application in view of the following remarks.

Claims 1, 3, 4, 6 and 22 are active in this application. Applicants' representative would like to thank Examiner Weber for the courteous and helpful discussion of the issues during the discussion held June 23, 2003. The following remarks summarize and further expand on the contents of that discussion.

The present invention relates to a method for inhibiting hair growth. The method comprises the topical application of a compound that is an inhibitor of elastase-like enzymes or a neutral endopeptidase inhibitor. The compound is further limited to not be a matrix metalloproteinase inhibitor and is limited to not be a mercaptopropionamide compound.

The claims stand rejected under 35 U.S.C. 112, first paragraph. The rejection is stated

in the Official Action as based on lack of enablement on the grounds that various references have been shown by the Examiner to disclose phosphonic acid derivatives that are also MMP inhibitors. The Examiner asserts that Applicants do not appear to have shown any suitable compounds in the specification that fall within the scope of the claims. However, as discussed with the Examiner, this is not the case. Applicants note that the compounds disclosed in the various references are various phosphonic acid derivatives. However, none of the references disclose phosphoramidate compounds, nor that phosphoramidate compounds would be MMP inhibitors.

The Examiner's attention is directed to page 5 of the specification which indicates a generic structure of a preferred embodiment of the present invention, namely phosphoramidate compounds. Among the specific examples in the present specification, Applicants point to Examples 1-6 which are particular phosphoramidate compounds. Applicants have performed the test for MMP inhibition on the compound of Example 1 and found that it does not inhibit MMP, while still having both elastase inhibitory activity and neutral endopeptidase inhibitory activity, as shown in the tables in the Examples of the present application.

Since none of the references recited by the Examiner disclose compounds with the phosphoramidate structure, the Examiner has no reasonable basis to assert that the other Examples 2-6 would not be expected to fall within the present claims.

Since Applicants have clearly shown a class of compounds that have the required properties of the claims, Applicants disclosure enables the present invention as claimed.

During the discussion of June 23, the Examiner indicated that his real concern is whether the application provides guidance to those of skill in the art to determine the scope of the claims without undue experimentation. As noted above, at least one recognized class of

compounds has been described by Applicants that has the required properties. Further, those of skill in the art are readily aware of the various classes of compounds that have elastase inhibitory or neutral endopeptidase inhibitory activity. The question of whether the compounds or classes of compounds would then be an inhibitor of MMP or not, is readily determined by a simple assay. Further, as the Examiner has shown by recitation of many references showing MMP inhibitors, various classes of compounds are also known to those of skill in the art to have MMP inhibitory activity. Accordingly, it is not an undue burden for one of skill in the art to know which types of compounds to test or which not to test. Further, that some experimentation may be involved does not mean that there is undue experimentation involved. In the *Hybritech Inc. v. Monoclonal Antibodies, Inc.* case (a copy of which is attached), the Federal Circuit clearly noted that enablement is not precluded even if some experimentation is required.[1] In that case, the patented claims were drawn to an assay that used monoclonal antibodies identified only by their affinity for an unspecified antigenic substance. This is analogous to the present claims in which the compound used in the present method is defined by its inhibitory activities, rather than by giving a specific or generic structure. At issue in the *Hybridoma* case was whether the screening process necessary to test the necessary characteristics of the monoclonal antibodies produced was undue experimentation. The court decided that it was not, since the ability to screen for the characteristics was well known by those in the art and was not unduly burdensome (even though monoclonal antibody production typically produces a multitude of species in an array, all of which would then necessarily have to be screened).

In the present case, as noted above, there are many classes of compounds that are known to be elastase inhibitory or neutral endopeptidase inhibitory, including the two classes

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1 *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir, 1986).

of compounds disclosed and discussed in the present application. In a preferred embodiment of the present invention, now the subject of the main claim, the compounds of the claim must also not be inhibitors of MMP. As noted above, the present application discloses phosphoramidate compounds having this property. With respect to other compounds that would fall within the claims, it is a simple matter for one of skill in the art to start with known elastase or neutral endopeptidase inhibitors, and determine whether the compounds have MMP inhibitory activity or not. Some compounds could be readily determined to be outside the claims by their disclosure in the art as MMP inhibitors, such as the various compounds in the references recited by the Examiner. Many of the classes of MMP inhibitor compounds are well known to those of skill in the art and would thus be readily eliminated from the scope of the claims.

Accordingly, the claims of the present invention are believed to meet all of the requirements of patentability, including but not limited to, the claims are definite, enabled, and provide adequate written description of the present invention. As such, there is no legal basis for the Examiner to continue to reject the present claims, absent some newly discovered art. As such, the rejection should be withdrawn.

Applicants submit that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

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